

REMARKS/ARGUMENTS

Status of Claims

Claims 1, 2, 5-10 and 12-20 were pending. Claims 1 and 17 have been amended and new claims 21 and 22 have been added. Therefore, upon entry of this amendment, which is respectfully requested, claims 1, 2, 5-10 and 12-22 will be pending.

35 USC §101 Rejections

Claims 1, 2, 5-10 and 12-20 were rejected under 35 U.S.C. 101 as because these claims are drawn to non-statutory subject matter. In particular, the Examiner indicated that claims 1 and 17 lack a "tangible" result. Applicants have amended claims 1 and 17 to recite "providing the statistically derived decision as output." It is respectfully asserted that claims 1 and 17 recite a concrete, tangible and useful result, as providing the decision as output, for example, provides useful information (the statistically derived decision) to assist with making a diagnosis. For example, the output may be stored in a memory, provided to a separate computer system or the like or, as further recited in new dependent claims 21 and 22, the output may be display data, *e.g.*, for rendering on a display screen. Support for these additions can be found, for example, at page 3 line 9 to page 4, line 2.

35 USC §112 Rejections

Claims 1, 2, 5-10 and 12-20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, in claims 1 and 17 the Examiner indicated that the language "obtained by subjecting", and similar language, with reference to a test data set and reference data sets, is unclear. Appropriate correction has been made by way of amendment to the claims.

Double Patenting Rejection

Claims 1-2, 7, 8 and 17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of co-pending Application No. 10/828,846. Applicants will reassess this provisional double patenting rejection when the claims are in condition for allowance but for the provisional double patenting rejection. If necessary or desired, Applicants will consider filing a terminal disclaimer at that time.

35 USC §103 Rejections

Claims 1, 12, 13, 14 and 17-20 were rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman *et al.*, Electrophoresis, 1995, Vol. 16, pp. 941-947 (hereinafter "Zimmerman"), in view of Kim *et al.*, IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, pp. 761-765 (hereinafter "Kim"), and further supported by Anderson *et al.*, WO/1999/039298; Filed 03/02/1999 (hereinafter "Anderson"). Claims 1, 2, 5-10 and 12-20 were also rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman in view of Kim, as applied to claims 1, 12, 13, 14 and 17-20 above, and further in view of Thompson. Applicants respectfully traverse these rejections.

Applicants respectfully assert that the cited references, either individually or in combination, fail to teach or suggest limitations of the claims. For example, the cited references fail to teach or suggest the limitation of "storing a plurality of reference data sets, including reference data sets that were obtained by subjecting biological samples of reference subjects **known to not have one of said one or more systemic autoimmune diseases** to said set of one or more tests" as recited in claim 1. (emphasis added) Similar limitations are presented in independent claim 17. Zimmerman, for example, reports on a study in which all patients have a disease of the study. For example, in the sentences on the right-hand column on page 941, it is stated that:

"Skeletal muscle samples were obtained at diagnostic biopsies in patients presenting with clinically suspected muscular disorders. ... Samples from patients with muscular dystrophy or polymyositis were used."

None of the individuals studied in Zimmerman was disease free. Also, Figures 3A, 3B and 3C as referenced by the Examiner do not equate to a teaching for values that are associated with neither disease as posited by the Examiner, especially not for stored reference data sets. Figure 3 illustrates histogram formation representing results of blot tests, not reference data sets for use in a comparison with a patient sample. That is, Zimmerman fails to teach or suggest reference data sets for disease-free patients.

Similarly, in Thompson, all tests are carried out on individuals/patients who did have SLE; no tests were carried out on patients known to not have an SLE variant, *i.e.*, known to be disease-free. This is clear with reference to Table I and the sentences spanning columns 15 and 16: "Data on 117 Caucasian patients with SLE were included in this study. Of these, 19 had a clinical diagnosis of incomplete lupus as previously defined; the remaining 96 had SLE fulfilling the American Rheumatism Association's revised criteria for the classification of the disease and two had drug induced lupus (Table I)." For profile D in the study, it is stated at page 17 that "[n]one of the patients with SLE included in this study had profile D...." Thus all patients in the study of Thompson had a form of SLE; none of the patients was disease-free.

Kim and Anderson also fail to remedy the deficiencies of Zimmerman and Thompson in this regard. In particular, these references also fail to teach or suggest, *inter alia*, the limitation of "storing a plurality of reference data sets , including... reference data sets that were obtained by subjecting biological samples of reference subjects **known to not have one of said one or more systemic autoimmune diseases** to said set of one or more tests " as recited in independent claim 1, and a similar limitation presented in claim 17. (emphasis added)

Accordingly, Applicants respectfully request withdrawal of the rejections to independent claims 1 and 17 for at least the above reasons. Applicants also respectfully request withdrawal of the rejections to all claims depending from claims 1 and 17, based at least on their dependency from claims 1 and 17.

It should be further noted that Applicants do not believe that one skilled in the art would be motivated to combine all the disparate references presented in the above rejections. Also, Applicants believe that such combinations would not result in the claimed invention, or

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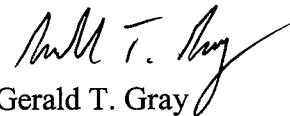
that such combinations would render the claimed invention obvious. Nonetheless, Applicants will withhold further argument and comment at this time as Applicants believe the pending claims are allowable based at least on the above reasons.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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